

REMARKS

In the Office Action, the Examiner noted that Claims 1-47 are pending in the application, of which Claims 1-47 are rejected.

By the present amendment Claims 1, 8, 38, 44-46 have been amended, new Claims 48-51 have been added, and Claims 2, 10, 14, 20-21 have been cancelled without prejudice to be prosecuted in other continuation or co-pending applications.

Thus, by the present amendment Claims 1, 3-9, 11-13, 15-19, and 22-51 are pending and under consideration. Reexamination and reconsideration of the claims, as amended, are respectfully requested.

**Claim Rejection under 35 U.S.C. §112**

In the Office Action Claims 46 and 47 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner stated that “it is unclear as to whether applicant is trying to form a dependent claim with “as in claim 15” on line 4, or is referring to a method in claim 15 (which does not exist).

Applicants have corrected the inadvertent error and amended the Claim 46 to recite “as in Claim 38 ... .”

Applicants believe that the present amendment obviates this rejection and request the withdrawal of the same.

**Claim Rejection under 35 U.S.C. §102**

In the Office Action, under 35 U.S.C. §102(b), the Examiner rejected:

- Claims 1-3, 7, 13, 15-18, 23, 25, 29-31, 37, 38, and 40-45 as being anticipated by Parodi (USPN 5,820,595);
- Claims 1-3, 5, 7, 13, 29, 36-40, and 43-45 as being anticipated by Schneider (USPN 5,836,967);

- Claims 1-9, 12-14, 19, 21, and 22 as being anticipated by Gharibadeh et al. (USPN 5,458,613);
- Claims 1-3, 8, 13, 16, 19, 20, 21, and 31 as being anticipated by Holman et al. (USPN 6,416,529);
- Claims 1-3, 7, 17, 34, 36, 40, 44, and 45 as being anticipated by Simpson et al. (USPN 5,462,529);
- Claims 1, 8, and 26-28 as being anticipated by Barbut et al. (USPN 5,989,281);
- Claims 1, 28, and 31-33 as being anticipated by Stack et al. (USPN 6,264,671); and
- Claims 1 and 35 as being anticipated by Houser et al. (USPN 5,865,801).

#### Claims 1-37

Claim 1 has been amended to incorporate the limitation of dependent Claim 21 (now canceled). Thus, Applicants will address the rejection of Claim 21. Claim 21 along with Claims 1-9, 12-14, 19, and 22 were rejected under 35 U.S.C. §102(b) as being anticipated by Gharibadeh and alternatively Holman.

For the rejection based on Gharibadeh, the Examiner stated that “The catheter body (11) includes an axial split (24) over a portion of the guidewire lumen (col 3, line 42). The inflation tube serves as a deployment shaft for the balloon, and the axial slit could be configured to receive a different tube.” However, the Office Action did not provide any explanation regarding the rejection of Claim 21.

Gharibadeh is directed to a balloon catheter adapted for rapid exchange and having an elongated catheter shaft with a guidewire lumen extending through the shaft and axial slit in the catheter shaft.

The present invention as originally recited in Claim 21, states that “the balloon catheter includes an axial slit formed over at least a portion of the length of the catheter body to removably receive an inflation tube of the balloon structure.”

Applicants respectfully would like to point out that although similar phrases (e.g., catheter shaft (11) of Gharibadeh and catheter body (12) of the present application) may have been used in the present application and Gharibadeh, these phrases (or nouns) refer to different elements. Gharibadeh's catheter shaft (11) refers to the catheter shaft in its entirety less the guidewire 28, whereas catheter body (12) in the present invention refers to an elongate body which is separable (e.g., removable) element from the balloon structure (14).

Applicants respectfully submit that Gharibadeh does not disclose, teach, or suggest, a catheter body with an axially slit passage and an inflation tube removably receivable therein. The slit in the guidewire lumen of the Gharibadeh only receives a guidewire and in fact has no access to the inflation tube which inflates the balloon. Assuming arguendo that the slit of Gharibadeh "could" receive a different tube (in place of a guidewire which is not a tube), such tube would be a tube different and separate from the inflation tube, since the inflation tube of Gharibadeh is an integral part of the catheter shaft (11) which includes the slit, thus it would not be possible for the inflation tube of Gharibadeh to be removably received in slit 24.

In contrast to Gharibadeh, as originally recited in Claim 21, the inflation tube of the present invention is removably receivable in the slit of the catheter body.

"Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." W.L. Gore & Associates v. Garlock, Inc., 220 USPQ 303, 313 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

By the present amendment independent Claim 1 has been amended to include substantially the limitations of Claim 21, and now recites, among other things: "a catheter body having ... an axially slit passage along at least a portion thereof; and a first balloon structure comprising a balloon and a passage slidably receivable over the catheter body and an inflation tube removably receivable in the axially slit passage."

Applicants respectfully submit that Claim 21 as originally filed and which contents have been substantially included in Claim 1 as presently amended are not

anticipated by or obvious in view of Gharibadeh and that they are patentably distinguishable over the same.

For rejection of Claim 21 based on Holman, the Examiner stated that "Holman includes an axial slit or spiral slit on any of the tubular members, which would include the catheter body (col 8, paragraph 5)."

Holman is directed to a balloon catheter having an expandable distal portion and balloon protector means comprising a first removable sleeve having a variable inner diameter to ease sliding the first sleeve over the balloon.

The present invention as originally recited in Claim 21, states that the balloon catheter includes an axial slit formed over at least a portion of the length of the catheter body to removably receive an inflation tube of the balloon structure."

Applicants respectfully submit that Holman does not disclose, teach, or suggest, a catheter body with axially slit passage and an inflation tube removably receivable therein." The slit (36) of Holman is located in the inner sleeve (28) which is positioned around balloon (22). The inner sleeve (28) is not a catheter body having a guidewire lumen and an axially slit passage along at least a portion of a length of the catheter body for removably receiving a an inflation tube of the balloon structure.

In contrast to Holman, as originally recited in Claim 21, the inflation tube is removably receivable in the slit of the catheter body.

By the present amendment independent Claim 1 has been amended to include substantially the limitations of Claim 21, and now recites, among other things: "a catheter body having ... an axially slit passage along at least a portion thereof; and a first balloon structure comprising a balloon and a passage slidably receivable over the catheter body and an inflation tube removably receivable in the axially slit passage."

Applicants respectfully submit that Claim 1 as amended, is not anticipated by or obvious in view of Holman and that it is patently distinguishable over the same.

Applicants respectfully request withdrawal of this rejection and the allowance of Claim 1 and all those depending directly or indirectly therefrom.

**Claims 38-47**

Independent Claims 38, 44, and 45 were rejected under 35 U.S.C. §102(b) as being anticipated by Parodi, and Schneider optionally in combination with Simpson. Claims 38, 44, and 45 have been amended to recite among other things substantially the limitations of Claim 1 as presently amended. Applicants respectfully submit that neither of the references, alone or in combination with one another, teach or suggest Claim 38, 44 and 45, as presently amended, and that these claims are patentably distinguishable over the references. As discussed above in reference with Claim 1, Applicants respectfully submit that the present amendments to Claims 38, 44, and 45 obviate the rejection of these claims.

Applicants respectfully request withdrawal of this rejection and the allowance of Claims 38, 44, and 45 and all those depending directly or indirectly therefrom.

**Claim Rejection under 35 U.S.C §103**

In the Office Action, under 35 U.S.C. §103(a), the Examiner rejected

- Claims 1 and 8-11 as being unpatentable over Gharibadeh in view of Holman et al.;
- Claims 1, 23, and 24 as being unpatentable over Parodi in view of Holman; and
- Claims 1, 15, 46, and 47 as being unpatentable over Parodi in view of Lewis (USPN 6,044,845).

As these obviousness rejections follow from the rejections for anticipation discussed above, it is believed that they have been overcome by incorporation of the limitations of prior dependent Claim 21 into the independent claims.

**New Claims**

By the present amendment, Applicants have added new Claims 48-51, support for which can be found in the application as originally filed. Applicants

respectfully submit that new Claims 48-51 define patentable subject matter and requests allowance thereof.

The Applicants believe that the pending claims are directed to patentable subject matter. Consideration and an early allowance thereof are earnestly solicited. Applicants are also submitting an IDS citing a patent recently included in a PCT Search Report on a related application.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

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**APPENDIX A**  
**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

1. (Amended) An intravascular balloon catheter comprising:  
a catheter body having a proximal end, a distal end, a guidewire lumen  
[therebetween], and an axially slit passage along at least a portion thereof; and  
a first balloon structure comprising a balloon and a passage slidably  
receivable over the catheter body and an inflation tube removably receivable in the  
axially slit passage.

**CANCEL CLAIM 2.**

8. (Amended) An intravascular balloon catheter as in claim 1,  
wherein the inflation tube extends proximally from the balloon when the balloon is  
disposed near the distal end of the catheter body.

**CANCEL CLAIM 10.**

**CANCEL CLAIM 14.**

**CANCEL CLAIM 20 AND 21.**

38. (Amended) A method for balloon exchange over a catheter body  
having at least a guidewire lumen and an axially slit passage along at least a portion of a  
length of the catheter body, said method comprising:  
retracting a first inflation tube from or through the axially slit passage to  
withdraw a first balloon structure over [a] the catheter body in a proximal direction,  
wherein said catheter body remains in place over a guidewire in the guidewire lumen of  
the catheter body in a blood vessel; and  
advancing a second inflation tube into or through the axially slit passage to  
introduce a second balloon structure over the catheter body in a distal direction, wherein

said catheter body remains in place over the guidewire in the guidewire lumen of the catheter body in a blood vessel.

44. (Amended) A method for balloon withdrawal over a catheter body having at least a guidewire lumen and an axially slit passage, said method comprising:  
retracting an inflation tube from or through the axially slit passage to withdraw a first balloon structure over [a] the catheter body in a proximal direction, wherein said catheter body remains in place over a guidewire in the guidewire lumen of the catheter body in a blood vessel.

45. (Amended) A method for balloon introduction over a catheter body having at least a guidewire lumen and an axially slit passage, said method comprising:  
retracting an inflation tube from or through the axially slit passage to withdraw [introducing] a first balloon structure over a the catheter body in a [distal] proximal direction, wherein said catheter body remains in place over [the] a guidewire in the guidewire lumen of the catheter body in a blood vessel.

**PLEASE CANCEL CLAIM 46.**



**APPENDIX B**  
**A COMPLETE SET OF PENDING CLAIMS**

1. (Amended) An intravascular balloon catheter comprising:  
a catheter body having a proximal end, a distal end, a guidewire lumen,  
and an axially slit passage along at least a portion thereof; and  
a first balloon structure comprising a balloon and a passage slidably  
receivable over the catheter body and an inflation tube removably receivable in the  
axially slit passage.

**CANCEL CLAIM 2.**

3. (As filed) An intravascular balloon catheter as in claim 1, wherein  
a perimeter of the catheter body has a circular, oblong, or elliptical shape.

4. (As filed) An intravascular balloon catheter as in claim 1, wherein  
the distal end of the catheter body is axially tapered for a length of at least 3 mm.

5. (As filed) An intravascular balloon catheter as in claim 1, further  
comprising an atraumatic tip at the distal end of the catheter body.

6. (As filed) An intravascular balloon catheter as in claim 1, wherein  
the catheter body is formed from a polymer material, a composite material, a braided  
material, or a metal material.

7. (As filed) An intravascular balloon catheter as in claim 1, wherein  
the catheter body comprises multiple tubular members coupled to one another.

8. (Amended) An intravascular balloon catheter as in claim 1,  
wherein the inflation tube extends proximally from the balloon when the balloon is  
disposed near the distal end of the catheter body.

9. (As filed) An intravascular balloon catheter as in claim 8, wherein the inflation tube has sufficient column strength to advance the balloon structure over the catheter body.

**CANCEL CLAIM 10.**

11. (As filed) An intravascular balloon catheter as in claim 10, wherein the groove has a length in the range from 10 cm to 150 cm and an opening in the range from 0.001 inches to 0.014 inches.

12. (As filed) An intravascular balloon catheter as in claim 8, wherein the inflation tube has a length in the range from 10 cm to 150 cm.

13. (As filed) An intravascular balloon catheter as in claim 1, wherein the catheter body has an inflation lumen which mates with an inflation port on the balloon structure wherein the balloon structure is disposed near the distal end of the catheter body.

**CANCEL CLAIM 14.**

15. (As filed) An intravascular balloon catheter as in claim 1, wherein the catheter body is substantially free from structure at the proximal end which would interfere with passage of the balloon structure over the proximal end of the catheter body.

16. (As filed) An intravascular balloon catheter as in claim 1, further comprising an expandable vascular prosthesis disposed over the first balloon structure.

17. (As filed) An intravascular balloon catheter system comprising a balloon catheter as in claim 1, further comprising a second balloon structure having a passage which is slidably receivable over the catheter body.

18. (As filed) An intravascular balloon catheter system as in claim 17, further comprising an expandable vascular prosthesis disposed over the second balloon structure.

19. (As filed) An intravascular balloon catheter as in claim 1, wherein the catheter body is axially slit over at least a portion of the length of the guidewire lumen.

**CANCEL CLAIM 20 AND 21.**

22. (As filed) An intravascular balloon catheter as in claim 1, wherein the catheter body has a length in the range from 50 cm to 200 cm, and outer diameter in the range from 1 F to 10 F, and a guidewire lumen diameter in the range from 0.2 mm to 2 mm.

23. (As filed) An intravascular balloon catheter as in claim 1, wherein the balloon structure further comprises an inner sleeve having an inflatable balloon disposed over an outer surface of the inner sleeve, wherein the passage is formed axially in the inner sleeve.

24. (As filed) An intravascular balloon catheter as in claim 23, wherein the inner sleeve has a length in the range from 3 cm to 50 cm and the inflatable balloon has a length in the range from 1 cm to 5 cm.

25. (As filed) An intravascular balloon catheter as in claim 23, wherein at least a portion of the inner sleeve is slidably receivable over the catheter body.

26. (As filed) An intravascular balloon catheter as in claim 1, further comprising a deployable embolic capture element on the catheter body.

27. (As filed) An intravascular balloon catheter as in claim 26, wherein the deployable embolic capture element is located within 20 cm of the distal end of the catheter body.

28. (As filed) An intravascular balloon catheter as in claim 1, further comprising a deployable embolic capture element on the first balloon structure.

29. (As filed) An intravascular balloon catheter as in claim 1, further comprising a second balloon on the catheter body.

30. (As filed) An intravascular balloon catheter as in claim 29, further comprising an expandable vascular prostheses disposed over the second balloon.

31. (As filed) An intravascular balloon catheter as in claim 1, further comprising a self-expanding vascular prosthesis on the catheter body.

32. (As filed) An intravascular balloon catheter as in claim 31, wherein the vascular prosthesis is distal the balloon structure in an unexpanded state.

33. (As filed) An intravascular balloon catheter as in claim 31, wherein the vascular prosthesis is at least partially under the balloon structure in an unexpanded state.

34. (As filed) An intravascular balloon catheter as in claim 1, further comprising an atherectomy element coupled to the distal end of the catheter body.

35. (As filed) An intravascular balloon catheter as in claim 1, further comprising at least one pressure sensor coupled to the distal end of the catheter body.

36. (As filed) An intravascular balloon catheter as in claim 1, further comprising at least one infusion port at the distal end of the catheter body.

37. (As filed) An intravascular balloon catheter as in claim 1, further comprising a second catheter body having a passage which is slidably receivable over the catheter body.

38. (Amended) A method for balloon exchange over a catheter body having at least a guidewire lumen and an axially slit passage along at least a portion of a length of the catheter body, said method comprising:

retracting a first inflation tube from or through the axially slit passage to withdraw a first balloon structure over the catheter body in a proximal direction, wherein said catheter body remains in place over a guidewire in the guidewire lumen of the catheter body in a blood vessel; and

advancing a second inflation tube into or through the axially slit passage to introduce a second balloon structure over the catheter body in a distal direction, wherein said catheter body remains in place over the guidewire in the guidewire lumen of the catheter body in a blood vessel.

39. (As filed) A method as in claim 38, wherein the balloon structure that is introduced over the catheter body is not the same as the balloon structure that is withdrawn over the catheter body.

40. (As filed) A method as in claim 38, further comprising expanding the first and second balloon structures which have been introduced to the blood vessel.

41. (As filed) A method as in claim 40, wherein at least one of the balloon structures are carrying a vascular prosthesis which is deployed into the blood vessel by balloon expansion.

42. (As filed) A method as in claim 40, wherein expanding the balloon structure comprises introducing an inflation medium through an inflation tube connected to the balloon structure.

43. (As filed) A method as in claim 40, wherein expanding the balloon structure comprises introducing an inflation medium through an inflation lumen in the catheter body.

44. (Amended) A method for balloon withdrawal over a catheter body having at least a guidewire lumen and an axially slit passage, said method comprising:  
retracting an inflation tube from or through the axially slit passage to withdraw a first balloon structure over the catheter body in a proximal direction, wherein said catheter body remains in place over a guidewire in the guidewire lumen of the catheter body in a blood vessel.

45. (Amended) A method for balloon introduction over a catheter body having at least a guidewire lumen and an axially slit passage, said method comprising:  
retracting an inflation tube from or through the axially slit passage to withdraw a first balloon structure over the catheter body in a proximal direction, wherein said catheter body remains in place over a guidewire in the guidewire lumen of the catheter body in a blood vessel.

**PLEASE CANCEL CLAIM 46.**

47. A kit as in claim 46, further comprising a second balloon.

48. (New) An intravascular balloon catheter comprising:  
a catheter body having a proximal end, a distal end, a guidewire lumen, and an axially slit passage therebetween; and  
a first balloon structure comprising a balloon and a deployment shaft, wherein the balloon has a passage which is slidably receivable over the catheter body and the deployment shaft is removably receivable in the axially slit passage of the catheter body.

49. (New) A method for balloon exchange over a catheter body having at least a guidewire lumen and an axially slit passage, said method comprising:  
retracting a deployment shaft from or through the axially slit passage to withdraw withdrawing a first balloon structure over a catheter body in a proximal direction, wherein said catheter body remains in place over a guidewire in the guidewire lumen of the catheter body in a blood vessel; and  
advancing a deployment shaft into or through the axially slit passage to introduce introducing a second balloon structure over the catheter body in a distal direction, wherein said catheter body remains in place over the guidewire in the guidewire lumen of the catheter body in a blood vessel.

50. (New) A method for balloon withdrawal over a catheter body having at least a guidewire lumen and an axially slit passage, said method comprising:  
retracting a deployment shaft from or through the axially slit passage to withdraw withdrawing a first balloon structure over a catheter body in a proximal direction, wherein said catheter body remains in place over a guidewire in the guidewire lumen of the catheter body in a blood vessel.

51. (New) A method for balloon introduction over a catheter body having at least a guidewire lumen and an axially slit passage, said method comprising:  
retracting a deployment shaft from or through the axially slit passage to withdraw introducing a first balloon structure over a catheter body in a proximal direction, wherein said catheter body remains in place over a guidewire in the guidewire lumen of the catheter body in a blood vessel.